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Display Date	10-30-98
Publication Date	11-2
Certifier	<i>[Signature]</i>

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**General and Plastic Surgery Devices Panel of the Medical Devices Advisory  
Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 17, 1998, 9 a.m. to 6 p.m.

*Location:* Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

*Contact Person:* David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12519. For up-to-date information on this meeting, please call the Information Line or access the Internet address at "<http://www.fda.gov/cdrh>".

*Agenda:* The committee will discuss and make recommendations on a proposal for the classification of preamendment wound dressing medical devices based on: (1) A proposed rule published in the **Federal Register** of September 19, 1989 (54 FR 38600); (2) comments received in response to the proposed rule; and (3) comments from the General and Plastic Surgery Devices Panel meeting of July 20, 1995. The committee will also discuss and make recommendations on

the reclassification of preamendment class III topical oxygen devices for wound healing on extremities based on information received from a call for safety and effectiveness information under section 515(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)) published in the **Federal Registers** of August 14, 1995, and June 13, 1997 (60 FR 41986 and 62 FR 32355, respectively).

*Procedure:* On November 17, 1998, from 9:30 a.m. to 6 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 3, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and between approximately 4 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 3, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On November 17, 1998, from 9 a.m. to 9:30 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.  
2).

Dated: October 27, 1998

MA Friedman

Michael A. Friedman  
Deputy Commissioner for Operations

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

**BILLING CODE 4160-01-F**

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*Aisha Borders*